DEPARTM

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10398 #57]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the "generic" clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are "usually voluntary, low-burden, and uncontroversial collections," do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. On October 23, 2011, OMB approved our initial request to use the generic clearance process under control number 0938–1148 (CMS-10398). It was last approved on April 26, 2021, via the standard PRA process which included the publication of 60- and 30-day **Federal Register** notices. The scope of the April 2021 umbrella accounts for Medicaid and CHIP State plan amendments, waivers, demonstrations, and reporting. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit comments regarding our burden estimates or any other aspect of this collection of information, including: the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 14 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting, please reference the applicable form number (see below) and the OMB control number (0938-1148). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to http://www.regulations.gov. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: CMS-10398 (#74)/OMB control number: 0938-1148

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may access CMS' Web Site at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collection

1. *Title of Information Collection:* Medicaid Section 1115 Substance Use Disorder

(SUD) Demonstration: Monitoring Reports Documents and Templates; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* On November 1, 2017, CMS released a letter #17-003 to all state Medicaid Directors announcing new directions on how CMS would like to work with states on section 1115(a) demonstrations to improve access to and quality of treatment for Medicaid beneficiaries as part of a Department-wide effort to combat the ongoing opioid crisis. The letter also announced that CMS is now offering a more flexible, streamlined approach to accelerate states' ability to respond to the national opioid crisis while enhancing states' monitoring and reporting of the impact of any changes implemented through these demonstrations.

Medicaid Section 1115 demonstration monitoring and evaluation Special Terms and Conditions (STC), and the letter #17-003, make clear that CMS remains committed to ensuring state accountability for the health and well-being of Medicaid enrollees and that monitoring and evaluation are important for understanding the outcomes and impacts of approaches to Medicaid SUD demonstrations. For this purpose, CMS is undertaking efforts to help states monitor the elements of these demonstrations, while giving them the flexibility to adapt to changing conditions in their states. States with approved SUD demonstrations are required to develop implementation and monitoring plans, including monitoring metrics, a monitoring protocol, and regular monitoring reports describing their implementation progress.

In addition, the STCs for these section 1115 demonstrations address that states are required to submit in their regular monitoring reports, information on milestones and performance measures that they elected to represent key indicators of progress toward meeting the goals for the demonstrations.

Furthermore, to improve the quality and efficiency of the reporting requirements for SUD demonstrations, CMS in conjunction with state advisory groups developed a set of standardized monitoring tools for states to use for their regular reporting, including:

- The Medicaid section 1115 SUD demonstration monitoring protocol template (this is one-time submission);

- The Medicaid section 1115 SUD demonstration monitoring protocol workbook (this is a one-time submission);
- The Medicaid section 1115 SUD demonstration monitoring report template, and;
- The Medicaid Section 1115 SUD demonstration monitoring report workbook.

As specified in official 1115 policy communications to states:

In accordance with 42 CFR 431.428 states must submit all post-approval deliverables as stipulated by CMS and within the timeframes outlined within the STCs for the specific Medicaid 1115 State Demonstration.

The State Medicaid Director Letter, #17-003, entitled, *Strategies Addressing the Opioid Epidemic*, provides a framework for SUD demonstrations under Medicaid Section 1115 Authority. This letter indicates that a state's application should confirm its commitment to assuring the necessary resources to support robust monitoring protocol and evaluation, and that the state will provide an implementation plan subject to CMS approval. The letter further states that information about the specific measures and reporting will be detailed in a monitoring protocol agreed upon by CMS and the state after approval of the demonstration which will demonstrate progress toward meeting the goals for this demonstration initiative.

In addition, the STCs for the Medicaid section 1115 SUD demonstrations require that approved states submit an SUD implementation plan subject to CMS approval, and an SUD monitoring protocol to be developed in cooperation with CMS and which is subject to CMS approval. The SUD monitoring protocol, reporting templates, and associated monitoring metrics flow down from the OMB-approved SUD implementation plan, which aligns with the goals and objectives of the demonstration as expressed in SMDL #17-003.

The STCs also require approved states to submit three quarterly and one annual monitoring reports consistent with the elements provided in 42 CFR 431.428 and in accordance with a framework to be provided by CMS. The STCs also provide that the monitoring framework be subject to change as monitoring systems are developed and evolve, and that states are required to

report in a structured manner that supports federal tracking and analysis.

In this 2022 information collection request, we have revised the following monitoring tools:

- Monitoring protocol tools:
  - Monitoring protocol workbook (updated to Version 6.0)
  - Monitoring protocol template (updated to Version 4.0)
- Monitoring report tools:
  - Monitoring report template (updated to Version 4.0)
  - Monitoring report workbook (updated to Version 6.0)

This 2022 release incorporates updated guidance on reporting metrics, narrative information, and other clarifications. This release also reflects modifications to align with the Medicaid Section 1115 Substance Use Disorder Demonstrations: Technical Specifications for Monitoring Metrics Manual Version 4.0 (released September 2021).

In addition, this release incorporates updated functionality in the Performance Metrics Database & Analytics (PMDA) system aimed to automate aspects of reporting and customize tools to ease state burden. Updated functionality includes:

- Auto-population of certain fields within the monitoring report tools in alignment with the state's CMS-approved monitoring protocol.
- Reporting flagged items early in the process to reduce resubmission and allow CMS to engage with the state faster and on a more detailed level.
- Ensuring the latest version of the monitoring tools are utilized by sending an e-mail notification to all designated demonstration contacts when customized monitoring report tools are available.

Form Number: CMS-10398 (#57) (OMB control number: 0938–1148); *Frequency:* Once, yearly, and quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 35; *Total Annual Responses:* 596; *Total Annual Hours:* 6,394. For policy questions regarding this collection contact: Danielle Daly at 410-786-0897.

Dated: February 18, 2022.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

[FR Doc. 2022-03936 Filed: 2/23/2022 8:45 am; Publication Date: 2/24/2022]